K062774

OCT 19 2006

Attachment 4

Belmont Instrument Corporation

Creating a New Standard of Care

Registered in Accordance with ISO 13485

Premarket Notification
510(k) Summary of Safety and Effectiveness
[As Required By 21 CFR 807.92(a)]

1. *Submitter & Manufacturing Site:* Belmont Instrument Corporation
780 Boston Road
Billerica, MA 01821

Establishment Registration Number: 1219702

2. *Contact Person:* Ms. Uraiwan P. Labadini, Quality Assurance/Regulatory Affairs Manager

Telephone: (978) 663-0212 Ext. 28 Fax: (978) 663-0214

3. *Trade Name:* Belmont ***buddy plus***™ *Fluid Warmer*

4. *Common name:* Nonelectromagnetic Blood or Fluid Warming Device

5. *Classification name:* Blood/Fluid Warmer

6. *Product Code:* 81BSB
Device Class: Classified as a Class II device per Federal Register July, 1978.

7. *Legally marketed predicate device to which substantial equivalence is claimed:*
Belmont Instrument Corporation Microheater marketed as Belmont ***buddy***™ *Fluid Warmer.*

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8. *Brief Description:* The Belmont **buddy plus**™ *Fluid Warmer* is a portable in-line blood and fluid warmer. It consists of three components, a heater unit, a power module which powers the heater unit and displays alarm and status messages, and a single-use disposable heat exchanger set. The power module also contains a built-in battery pack which automatically switches over to the battery operation when the AC power is disconnected. When the power is restored, the system reverts to AC power automatically, the battery charger is activated, and the battery is charged. The heating technology used is resistive heating of two plates within the heater unit.

The **buddy plus**™ *Fluid Warmer* warms intra-venous fluids, including blood and blood products, to physiological temperature, and monitors fluid temperature. It also senses lack of IV fluid flow, or empty set, and a number of internal fault conditions including over-heating, loss of electrical connection to the heater, and failure to heat. The device stops heating and alarms if an alarm or fault condition occurs. The system provides the user with alarm, alarm message, temperature, and other operating information via a bright alphanumeric display.

The sterile disposable set is placed in-line between a standard IV line at its input and a user-supplied cannula or IV infusion set at its output. The input can come from a gravity fed IV line with roller clamp and drip chamber, external to the device and not supplied by Belmont Instrument Corp.

The device is intended for low flow applications where the flow rate is 6 liter/hour (100 ml/min) or less.

9. *Intended Use:* The **buddy plus**™ *Fluid Warmer* intended use is for warming blood, blood products and intravenous solution prior to administration. It is intended to be used by healthcare professionals in clinical environments to prevent hypothermia.

10. *Summary of the technological characteristics of the Belmont* **buddy plus**™ *Fluid Warmer:*

The heater unit is powered with 16.5 VDC which is derived from 120 VAC, 50/60 Hz power supply with 12 volt battery back-up. The temperature of the infused fluids, visual and audible alarms, and other performance characteristics of the heater unit are controlled electronically. The disposable set consists of a molded frame to which a plastic film is bonded to one side and a microporous membrane is bonded to the other to form the fluid path. The disposable set has a sterile, non-pyrogenic fluid path, and is for single-patient use only.

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11. *Summary of Nonclinical Tests and Results*

In order to verify performance of the Belmont ***buddy plus***™ *Fluid Warmer* in support of substantial equivalence, the following tests were carried out:

a. Verify the ability of the system to warm cold fluids to physiological temperature.

b. Verify the ability of the system to protect the patient and to detect and alarm at unsafe or ineffective operating conditions.

12. Conclusion: The modified Belmont ***buddy plus***™ *Fluid Warmer* Blood/Fluid Warmer is substantially equivalent to the ***buddy***™ *Fluid Warmer* which received 510(k) approval on July 2, 2003. Both systems have the same intended use, and are capable of heating blood products or intravenous fluids to physiological temperature. Both systems perform as intended according to the specifications of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2006

Ms. Uraiwan P. Labadini
Quality Assurance/Regulatory Affairs Manager
Belmont Instrument Corporation
780 Boston Road
Billerica, Massachusetts 01821

Re: K062774
Trade/Device Name: Belmont *buddy plus*™ Fluid Warmer
Regulation Number: 21 CFR 864.9205
Regulation Name: Blood and Plasma Warming Device
Regulatory Class: II
Product Code: BSB
Dated: September 15, 2006
Received: September 22, 2006

Dear Ms. Labadini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

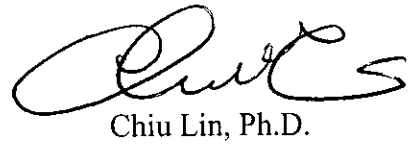
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062774

Device Name: Belmont ***buddy plus***™ Fluid Warmer

Indications For Use:

buddy plus™ Fluid Warmer intended use is for warming blood, blood products and intravenous solution prior to administration. It is intended to be used by healthcare professionals in clinical environments to prevent hypothermia.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for DOW 10/19/06

...sion Sign-Off)
...ision of Anesthesiology, General Hospital,
...ection Control, Dental Devices

...(k) Number: K062774